ENVIRONMENTAL IMPACT ANALYSIS REPORT

A. Date: March 13, 1981

B. Name of applicant/petitioner: American Feed Manufacturers Association

C. Address: 1701 N. Ft. Myer Drive
Arlington, Virginia 22209

D. Environmental information:

1. Proposed Action

It is proposed that supplemental selenium, in the form of sodium selenite or sodium selenate, be added to duck feeds at levels up to 0.1 ppm on a complete feed or total ration basis. This practice is identical with that currently permitted by § 573.920 - Selenium, with respect to growing chickens, swine, sheep, dairy cattle, and beef cattle.

a. Purpose - The purpose of the proposed action is to insure duck diets are fully adequate in this essential nutrient, and thereby prevent selenium deficiency problems.

b. Environment affected - Environments that theoretically could be affected are feed mills, duck feeding facilities, and land and water exposed to duck wastes. (See (2) below)

2. Probable Impact on the Environment

In view of the fact selenium is a natural constituent of soils, water, plants, and animal tissues, plus the minimal amount of selenium that will be involved and the very low concentrations found in feed and in duck wastes, no impact is expected on the environment. The following comments illustrate the basis of this belief.

The U.S. duck industry's average annual production is approximately 16-18 million. Feed consumption is reported to range from 2.65-3.00 pounds of feed per pound of live weight gain. Ducks are marketed at weights of 5 to 7 pounds, probably averaging about

6 pounds. Total feed consumption is calculated $\left(\frac{6 \times 3 \times 18 \text{ million}}{2000}\right)$ to be 162,000 tons.

Fortifying every ton of feed with the maximum 90.8 milligrams of selenium will require 32.4 pounds of selenium. This is equivalent to 72 pounds of sodium selenite containing 45% selenium.

Total U.S. use of selenium is estimated to be about 618 metric tons, based on U.S. Bureau of Mines figures for 1978. Domestic production represented about 209 metric tons, with the balance of the 408 metric tons supplied by imports. AFMA has previously estimated a use of 5.8 metric tons of selenium for non-ruminants (including layers - 1972) and 16.8 metric tons for ruminants (1976), for a total of 22.6 metric tons. The effect, if any, of an additional 32.4 pounds of selenium for ducks will be insignificant in an overall sense.

a. Adverse and Beneficial Effects - The relatively small amount of selenium involved, estimated to be 32.4 pounds, makes an evaluation of any environmental effect difficult. Assuming the same principles utilized in the analysis presented in AFMA's 1972 report on non-ruminants, and the subsequent conclusions, any effects would be increased by only 0.0025%. This would also be true of the Agency's related impact statement published in 1974.

If total estimated feed use of selenium is considered, 32.4 pounds represents a 0.00065% increase.

Rather than repeat the discussions contained therein, reference is made to the environmental reports submitted by AFMA in 1972 and 1976, and the environmental statement of 1974 prepared and published by the Agency.

b. Measures to Avoid or Mitigate Adverse Environmental Effects - No measures, other than good manufacturing practices (premixes and feeds), good animal husbandry practices, and good agronomy practices (wastes), are contemplated as being necessary.

c. Environmental Impact on Selenium Manufacturing - Since selenium is a by-product of copper refining, and domestic production meets only a third of total needs, there is no effect on domestic production. Any increase in selenium use must be met by foreign production. The amount involved precludes any measurable impact on that production.

3. Probable Unavoidable Adverse Environmental Effects

None believed to exist.

4. Alternatives to Proposed Action.

Alternatives to feed supplementation have been discussed in detail in AFMA's reports of 1972 and 1976, and in FDA's statement of 1974. Reference is made to these discussions which concluded feed supplementation was the most feasible means of supplying supplemental selenium.

5. Relationship between Use of the Environment and Long Term Productivity.

Reference is made to this section in the 1972 and 1976 reports, and the 1974 statement. We are not aware of any information that would change these statements.

6. Commitment of Resources.

Reference is made to this section in the 1972 and 1976 reports, and the 1974 statement. We are not aware of the information that would change these statements.

7. Objections of Other Agencies, Organizations, or Individuals.

We are not aware of environmental type objections on the part of other agencies, organizations, or individuals to the use of selenium at nutritional levels in animal feeds.

8. Proposed action relative to publication of an environmental statement.

The information presented in this environmental report documents the minimal amount of selenium that will be involved in supplementing duck feeds and the fact no environmental impact can be expected. Thus, we believe there is no need for an environmental statement. Should the Agency decide a statement should be prepared, we believe these same facts support approval of the requested action without tying same to the publication of either a draft or final statement.

9. Risk-benefit Analysis

We believe the extensive review of possible risk factors covered in the 1972 and 1976 AFMA reports, the 1974 FDA statement, and a recent review by FDA connected with AFMA's petition for layers, more than adequately documents a conclusion of no risk connected with supplementing animal feeds with selenium. The benefits of animal diets that are fully adequate in selenium have also been documented. The benefits to ducks - and the detriments connected with deficiency - are illustrated in the research reports contained in AFMA's petition for approval of supplemental selenium in duck feeds.

The cost of fortifying a ton of complete feed with 90.8 milligrams of selenium averages, according to an industry source, about 6 cents. The benefits are improved animal health and productivity as shown in the research reports contained in AFMA's petition.

E. Certification: The undersigned applicant/petitioner certifies the information furnished in this Environmental Impact Analysis Report is true, accurate, and complete to the best of his knowledge.

March 13, 1981

Lee H. Boyd
Vice President

AMERICAN FEED MANUFACTURERS ASSOCIATION, INC.
afma

WASHINGTON OFFICE
1725 K STREET, N.W.
WASHINGTON, D.C. 20006
TELEPHONE: 202: 296-1760

July 26, 1972

RECEIVED
BUREAU OF VETERINARY MEDICINE
JUL 31 1972

F 34331

Dr. C.D. Van Houweling, Director
Bureau of Veterinary Medicine, FDA
Parklawn Building
Rockville, Maryland 20852

Dear Dr. Van Houweling:

With reference to our phone conversation on Monday of this week, please find enclosed an Environmental Impact Analysis Report pertaining to our food additive petition for selenium supplementation of animal feeds. This Report is filed under the provisions of the proposed regulations on environmental impact considerations published in the Federal Register of July 12, 1972. Its contents can be summarized with the statement there will be no significant impact on the environment resulting from the supplementation of animal feeds with selenium as proposed in our petition.

Our petition dates from March 9, 1970. We have previously supplied all requested information and made agreed-upon changes to the petition itself. With the submission of this Report, we are supplying information under proposed regulations published as such only this month. We believe we have, indeed, gone the extra mile. We have willingly done so in the interests of animal agriculture and consumers of food of animal origin.

There is no question that selenium is an essential element for animals, that there is a deficiency in a substantial portion of the U.S., that the only feasible means of remedying this deficiency is to supplement feeds with minute amounts of sodium selenite or sodium selenate as proposed, and that said supplementation will benefit animal health and prevent needless mortality. We believe it self-evident that healthy animals nourished on a diet that is adequate in all nutritional aspects are a superior, more economical source of food for humans.

With respect to safety, this goes hand in hand with basic nutrition. The safest procedure of which we are aware to insure good animal health is to provide the required amounts of all essential nutrients. In particular, we know of no question based on fact concerning the safety of supplementing feeds with minute amounts of sodium selenite or sodium selenate.

RECEIPT ACKNOWLEDGED
JUL 31 1972
Bureau of Veterinary Medicine
Food and Drug Administration
Dept. of Health, Education, & Welfare

HEADQUARTERS OFFICE: 53 WEST JACKSON BOULEVARD, CHICAGO, ILLINOIS 60604 • TELEPHONE: 312: 427-2046

While supplementing feeds will have no significant impact on the environment, it will have a significant positive impact on animal health. An impact in keeping with the spirit of the Food, Drug, and Cosmetic Act. With the increasing problems of selenium deficiencies in animals, it is imperative our petition be approved as quickly as possible.

Sincerely,

Lee H. Boyd, Director
Feed Control and Nutrition

LHB/msg
Enclosure

afma AMERICAN FEED MANUFACTURERS ASSOCIATION, INC.

WASHINGTON OFFICE
1725 K STREET, N.W.
WASHINGTON, D.C. 20006
TELEPHONE: 202: 296-1760

COPY

ENVIRONMENTAL IMPACT ANALYSIS REPORT

Date: July 26, 1972

Name of Applicant: American Feed Manufacturers Association, Inc.

Address: 1725 K Street, N.W.
Washington, D.C. 20006

Note: New address on August 1, 1972 will be --
1701 N. Ft. Myer Drive
Arlington, Virginia 22209

HEADQUARTERS OFFICE: 53 WEST JACKSON BOULEVARD, CHICAGO, ILLINOIS 60604 • TELEPHONE: 312: 427-0046

This Environmental Impact Analysis Report is filed in accordance with the proposed new Part 6 - Environmental Impact Considerations, Title 21, Chapter I, published in the Federal Register of July 12, 1972.

The Report pertains to a petition of the American Feed Manufacturers Association originally submitted on March 9, 1970, amended on December 21, 1970, and subsequently amended and filed as a food additive petition on May 12, 1971.

1. Describe the Proposed Action:

The American Feed Manufacturers Association has filed a petition requesting feed manufacturers be permitted to add selenium, from sodium selenite or sodium selnate, to feeds to meet the nutritional requirements of chickens, turkeys, and swine for this essential element. With respect to chickens, this petition has been interpreted as applicable to chickens to 16 weeks of age.

The level of selenium added normally will not exceed 0.1 ppm in feeds for chickens and swine and 0.2 ppm in feeds for turkeys. These are the maximum levels originally requested in the AFMA petition. An amendment agreed upon with the Food and Drug Administration revised these figures to a total basis (natural plus added) maximum of 0.25 ppm and 0.35 ppm, respectively.

2. Discuss the Probable Impact of the Action on the Environment. (Including primary and secondary consequences):

Selenium deficiency symptoms in animals have become more prevalent during the past 10 years, indicating either a decrease in the dietary intake or a need for a greater concentration in the diet of the animals. The proposed food additive regulation anticipates the addition of selenium from sodium selenite or sodium selenate to feeds to supply adequate amounts of this essential nutrient in the diets of turkeys, chickens, and swine. Since it would be added to feed for animals rather than directly to the environment, there would be no direct or primary impact upon the environment.

The addition of selenium to the ration may, however, result in an increase in the selenium level excreted by the animals receiving the supplemental selenium. It is emphasized, however, that the proposed supplementation is designed to bring the level of selenium in the ration up to that required as an essential nutrient for the species involved. It does not anticipate the addition of selenium at levels higher than those necessary to insure an adequate amount of this essential nutrient, nor at levels higher than occur naturally in many areas of the country.

While laying chickens are not considered included in the present AFMA petition, information is being developed to substantiate an appropriate future petition. Consequently, layers have been included in the considerations covered in this and other sections.

The level of selenium added to the soil from feces and urine would be insignificant. The following calculations are based on assumptions which are known to be extreme. The actual impact upon the environment would be even less than is presented here. The assumptions are:

(a) Assume that all of the added selenium is excreted by the animal. (Selenium is an essential nutrient and, therefore, some is retained by the animal to meet its biochemical requirement.)

(b) Assume that five tons of dry matter from manure (feces and urine combined) per acre is applied to the soil. This is the highest practical rate of application. Normal rates of application are lower.

(c) Assume that none of the selenium leaches from the soil. (Selenium compounds are water soluble and, therefore, a certain amount would leach from the soil although the quantity is not known.)

(d) Assume that 40% of the dietary dry matter is excreted as manure.

The highest level of supplemental selenium permitted on a practical basis by this petition would be 0.2 ppm in turkey rations. If all of this were passed into the manure with 40% of the dietary matter excreted, the level of selenium in the manure from 0.2 ppm added selenium would be 0.5 ppm selenium on a dry matter basis. Converted to a ton basis, a ton of dry turkey manure would contain 0.4545 grams selenium from the added selenium. The application of 5 tons of dry turkey manure per acre would add only 2.27 grams selenium per acre.

In normal farming practices, the manure would be worked into the top 6 inches of soil. The top 6 inches of soil per acre weighs 2,000,000 pounds (1) or 909,000 kilograms. Therefore, 2.27 grams increase in selenium per 909,000 kilograms is equivalent to an increase in selenium content of 0.0025 ppm from the 5 tons of turkey manure.

The petition would provide for practical addition of up to 0.1 ppm added selenium for chicken and swine rations. This is 1/2 the amount used for turkeys. Therefore, 5 tons of dry manure from chickens and swine would supply 1.136 grams per acre or 0.0012 ppm.

Single application of 900 grams selenium per acre from sodium selenite have been added without detrimental effects to sheep fed forages grown on the treated soil (2). Sheep are known to be among the most sensitive animals to selenium.

Stated another way, the annual addition of 2.27 grams selenium per acre would require 396 years to equal the 900 grams per acre selenium addition referred to above, assuming that all the selenium is accumulated in the top 6 inches of soil.

Since soils in many areas of the United States are deficient in selenium, and since the manure is applied to the soil in the area in which the animals are grown, the effect, if any, of the addition of the small amounts of selenium would be beneficial to the animal consuming the forages and grains grown on these soils.

Reference has been made previously in this discussion to an assumption that none of the selenium is leached from the soil, and that information is not available concerning the amount of selenium which may be leached from the manure applied to the soil. However, for the purposes of the following discussion, we shall assume that all of the selenium from the manure is leached from the soil and would, therefore, find its way into the waterways of the United States. The actual fact is somewhere between these two extremes.

The area of the United States which will require selenium supplementation due to deficient levels in grains and feedstuffs comprises the Eastern United States and West Coast area of California, Oregon, and Washington. The Eastern United States is defined as the area East of the western borders of the following states: Minnesota, Iowa, Missouri, Arkansas, and Louisiana. Of the states in the above described deficient areas, California has the lowest mean annual rainfall of 24 inches (3). For the purposes of this discussion, we are also assuming the addition of 5 tons of dry manure per acre contributing the same levels of selenium per acre referred to above (i.e., 2.27 grams from turkey manure and 1.136 grams from chicken and swine manure). Twenty-four inches of rainfall would be equivalent to 2,467,051 kilograms water per acre. Therefore, if the amount of selenium added by 5 tons of dry turkey manure (2.27 grams) is assumed to be totally leached out of the soil by the 24 inches of rainfall (2,467,051 kilograms) this would give a selenium concentration of 0.00092 ppm in the water.

Using the same figures for chickens and swine, manure from these species would contribute half the level or 0.00046 ppm selenium in the water.

There is an insufficient quantity of manure produced by all of the chickens, turkeys, and swine in the Eastern United States and Pacific Coast areas to apply 5 tons to each acre of land in farms. The total manure production of turkeys, chickens, and swine in the Eastern United States and Pacific Coast area is given in Table 1. The total manure produced annually would be 1,418,839 tons for turkeys and 22,793,205 tons for chickens and swine combined. If this were spread at a rate of 5 tons per acre, then the turkey manure would cover 283,768 acres or 0.0557% of the land in farms in the Eastern United States and Pacific Coast regions (509,815,551 acres) (4). The number of acres to which chicken and swine manure could be added at the rate of 5 tons per acre is 4,558,641 acres or 0.8959% of the land in farms.

The animal population in the areas in which selenium supplementation is required is given by species in Table 2 with the level of selenium which would be consumed at the proposed added selenium levels of 0.2 ppm for turkeys and 0.1 ppm for chickens and swine. The combined total selenium consumption for all species grown in the Eastern United States and Pacific Coast areas is 5,815,780 grams. Assuming all of the animals in these areas were given supplemental selenium, this would be the total possible selenium which could be added back to the land through the manure.

If the total amount of possible selenium present in the manure (5,815,780 grams) is spread over the entire land area in farms in the same area of the United States (4) (509,815,551 acres), the amount of selenium added per acre per year would be 0.0114 grams. This would add 0.000012 ppm selenium to the top 6 inches of soil.

The earth's crust is calculated to contain 0.09 ppm selenium (5). The addition of 0.000012 ppm selenium to the soil through the manure from the supplementation of poultry and swine rations would amount to only 0.0133% of the selenium present in the earth's crust for that area.

Soils in areas where selenium deficiency diseases occur are reported to contain 0.04 ppm selenium or less and areas of moderate selenium content where selenium deficiency diseases do not occur contain 0.5 ppm to 5.0 ppm (6). The addition of 0.000012 ppm selenium to soil containing low selenium levels (0.04 ppm) would only increase the selenium content 0.03%. Adding 0.000012 ppm to the soils containing the lower limit of selenium for moderate selenium content soils (0.5 ppm) would increase the selenium content 0.0024%.

The maximum effect on the water as a result of total leaching out of the selenium from the manure by an annual rainfall of 24 inches would be insignificant. We have used 24 inches rainfall because this is the lowest mean annual rainfall of any state in which supplementation is necessary (3). Other states have higher annual rainfall. Using 2,457,051 kilograms water per acre from the 24 inches of rainfall and 0.0114 grams selenium added per acre on farm land, the water concentration of selenium would be 0.00000462 ppm. The average concentration of selenium for the waters of the entire area would be lower than this since the average rainfall is greater than 24 inches annually and would be further diluted with water from land which is not in farms.

The United States Department of Health has established 0.01 ppm selenium as a safe upper limit for human water supplies (7). The selenium content of sea water has been calculated to be 0.00009 ppm based upon analyses results from the Atlantic, Pacific, Antarctic Oceans, Long Island Sound and the Caribbean (8). This indicates that the maximum level of selenium leached out of the soil from returning manure containing added selenium from sodium selenite or sodium selenate would be insignificant. It would be safe for both humans and aquatic life even at the maximum possible levels.

TABLE #1

Annual manure production in the Eastern U.S. 1/ and Pacific Coast Areas by species:

SPECIES	LBS. FEED/ ANIMAL	# ANIMALS ANNUALLY	TOTAL POUNDS FEED CONSUMED	TOTAL LBS. DRY MANURE PRODUCED	TOTAL TONS MANURE ANNUALLY
		1000's	1000's	1000's	
Turkey Growing 2a/	65	101,353	6,587,945	2,635,178	1,317,589
Turkey Breeder 2b/	150	3,375	506,250	202,500	101,250
TOTAL TURKEY MANURE					1,418,839
Laying Hens 2c/	80	285,520	22,841,600	9,136,640	4,568,320
Pullet Replacements 2c/	15	285,520	4,282,800	1,713,120	856,560
Broiler Chickens 2d/	9.0	2,741,614	24,674,526	9,869,810	4,934,905
Swine Growing 2e/	600	80,695.4	48,417,240	19,366,896	9,683,448
Swine Breeders 2e/	2300	5,978.2	13,749,860	5,499,944	2,749,972
TOTAL CHICKEN AND SWINE					22,793,205

1/ Includes all states east of the western borders of Minnesota, Iowa, Missouri, Arkansas and Louisiana and the states of California, Oregon and Washington.

2/ Based on data published by Crop Reporting Board, SRS USDA.

a) Turkeys crop for 1971, April 1972
b) Total U.S. Turkey Breeders on farms, Dec. 1, 1971, Egg Chicken and Turkey Report - Jan. 1972.
c) Average number of chicken hens on hand in 1971 - Feb. 1972 report.
d) Number of broilers reported for 1971, April 1972.
e) Number of pigs produced in 1971, Report - Dec. 1971.

Table #2:

Annual consumption of added selenium at proposed added levels by species for the Eastern U.S. 1/ and Pacific Coast areas.

SPECIES	FEED CONSUMED PER ANIMAL	# ANIMALS IN AREA	SUPPLEMENTAL SE LEVEL	TOTAL SELENIUM CONSUMED
	Lbs.	1000's	ppm	gm.
Turkey Growing 2/	65.0	101,353.0	0.20	597,982.7
Turkey Breeders 2/	150.0	3,375.0	0.20	45,967.5
Laying Hens 2/	80.0	285,520.0	0.10	1,036,437.6
Pullet Replacements 2/	15.0	285,520.0	0.10	194,439.1
Broiler Chickens 2/	9.0	2,741,614.0	0.10	1,118,578.5
Hogs, Growing 2/	600.0	80,695.4	0.10	2,198,131.8
Sows 2/	2,300.0	5,978.2	0.10	624,243.6
TOTAL				5,815,780.8

1/ Includes all states east of the western borders of Minnesota, Iowa, Missouri, Arkansas, Louisiana, and the states of California, Oregon and Washington.

2/ See footnote (2/) Table 1.

References:

(1) Soil Chemical Analyses; M.L. Jackson; Prentice Hall, Inc.; Englewood Cliffs, N.J.

(2) Selenium in Nutrition, Subcommittee on Selenium, Committee on Animal Nutrition, Agricultural Board, National Research Council, National Academy of Sciences, Washington, D.C., 1971 - Pages 56-59.

(3) Miller, David W., Water Atlas of the United States, 1973, 2nd Edition, Water Information Center, Inc.; Port Washington, N.Y.

(4) United States Census of Agriculture, 1964, Volume 2, Chapter 1, Farms and Lands in Farms, Page 24, U.S. Department of Commerce, Bureau of the Census.

(5) Mitchell, R.L., Trace Elements in Soils, Chemistry of the Soil 2nd Edition, Page 322, Reinhold Publishing Company, N.Y., N.Y.

(6) Allaway, N.H., 1968, Control of the Environmental Levels of Selenium. Proceedings of the University of Missouri - 2nd Annual Conference on Trace Substances in Environmental Health, Pages 181-206.

(7) U.S. Department of Health, Education and Welfare, 1962, Drinking Water Standards. Public Health Service Publication 956.

(8) Schutz, D.F. and K.K. Turekian, 1965, The Investigation of the Geographical and Vertical Distribution of Several Trace Elements in Sea Water Using Neutron Activation Analysis. Geochim et Cismochim Acto 29:259-313.

3. Discuss the Probable Adverse Environmental Effects Which Cannot be Avoided:

Based upon the discussion in paragraph 2 above, no adverse environmental effects are anticipated.

4. Give Alternatives to the Proposed Action:

There is no known feasible alternative for adding inorganic selenium as a source of this essential nutrient in the diet of animals.

An apparent alternative would be the use of natural feed ingredients produced in areas of the country where the selenium content of ingredients exceeds the dietary requirement of animals. These, however, are not the major grain producing areas. The total supply of ingredients from these areas is insufficient to meet the nutritional requirements in all areas of the United States.

There is no known natural ingredient that provides a concentrated source of biologically available selenium.

Therefore, there is no suitable alternative to supplementing feeds for chickens, turkeys, and swine with sodium selenite or sodium selenate as proposed in the food additive petition.

5. Describe the Relationship Between Local Short Term Uses of Environmental and Maintenance and Enhancement of Long-Term Productivity.

There would be no long-term detrimental effects on the environment of supplementing animal rations with selenium due to the very low level of addition to the soil of selenium from manure. Assuming, as discussed in Section 2 (pg 4), the application of 0.000012 ppm annually, it would require:

(a) 75 years to change the selenium content of the farmland in the affected area by 1% when soil contains 0.09 ppm selenium (1).

(b) 33 years for a 1% change in low selenium soils containing 0.04 ppm (2).

(c) 416 years for a 1% change in soils containing moderate selenium levels (0.5 ppm) (2).

It is a well-established fact that selenium as sodium selenite is water soluble and would not be accumulated in the soil.

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(1) Mitchell, R.L. 1964, Trace Elements in Soils, Chemistry of Soil. Second Edition - Page 322. Reinholt Publishing Company, N.Y., N.Y.

(2) Allaway, N.H., 1968, Control of the Environmental Levels of Selenium. Proceeding of the University of Missouri - 2nd Annual Conference on Trace Substances in Environmental Health Pages 181-206.

The long-term beneficial effects can be more readily postulated since the selenium will be added to rations in areas whose soils are deficient. The addition of selenium to these soils would help to minimize soil depletion occurring through intensive farming and natural leaching of selenium from the soil. The incidence of selenium deficiency diseases has become progressively more severe and widespread in poultry, swine, cattle and sheep. Unless dietary supplementation of selenium is initiated, a reduction in animal production can be expected due to death and morbidity. This would in turn result in a decrease in animal protein in the human diet as well as reducing the selenium content of that diet. This could be expected to result in similar selenium deficiency diseases developing in the human population unless supplementation is initiated.

6. Describe Any Irreversible and Irretreivable Commitment of Resources:

Based on the usage level of this feed additive there would be no Irreversible or Irretreivable commitment of natural resources.

Selenium is obtained from mined ore as a by-product of the copper smelting process. The use of selenium salts in animal feeds further distributes the selenium and eventually returns it to the earth's crust, as discussed in paragraph 2. The amounts of selenium added to the soil (as manure is spread) or to stream and ground water (as selenium is subsequently leached from the soil) would be no more than the natural selenium present in the soil or water of areas in the United States where selenium is present at normal levels.

7. Discuss the Objections Raised by Other Agencies, Organizations or Individuals:

We know of no agencies, organizations or individuals who have questioned the effect on the environment of the use of selenium at nutritional levels in feeds for chickens, turkeys and swine.

8. If Proposed Action Should be Taken Prior to 90 Days from the Circulation of a Draft Environmental Impact Statement or 30 Days from the Filing of A Final Environmental Impact Statement, Explain Why:

The information presented in this environmental impact analysis report documents that there is no major effect upon the environment and, hence no need for an environmental impact statement.

A critical situation presently exists in identified areas of the United States which are deficient in selenium. An increasing number of cases of selenium deficiency are being diagnoxed by competent veterinarians. It is estimated that 25% of the turkeys are affected by selenium deficiency, showing up to a 10% higher mortality to 4 weeks of age. Fifty percent of the turkeys show impaired growth and feed conversion with additional losses in reduced grade and increased feed costs.

It is estimated that 5% of the broilers are affected to the extent of showing 3% higher mortality to 4 weeks of age. Twenty-five percent show impaired growth and feed conversion. The estimated annual loss to broiler producers is over $15,000,000.

It is estimated that 5% of the replacement pullets are affected to the extent of showing 3% higher mortality to 6 weeks of age, 10% of the laying hens show reduced egg production and impaired feed conversion. The estimated loss to the poultry and egg producers is almost $7 million.

See the attached report entitled "Economic Significance of Selenium Deficiency in Poultry Feeds" for a more detailed study. The number of birds used in this economic comparison is less than noted in Section 2 of this report since it is recognized that all birds in the selenium deficient geographic areas are not equally affected. The economic evaluation considers minimum numbers of animals affected while the environmental evaluation is based on maximum numbers of animals that might receive supplemental selenium.

In view of the need for selenium supplementation of feeds and the fact there is no significant impact on the environment, the proposed food additive regulation should go into effect as quickly as possible.

ECONOMIC SIGNIFICA _ OF SELENIUM DEFICIENCY IN POU ?Y FEEDS

Agricultural statistics (USDA 1970) show approximately 65% of the laying hens, 55% of the broilers and 50% of the turkeys are produced in "selenium deficient" states (Table I). These percentages have been used in subsequent calculations to estimate numbers of birds affected by selenium deficient diets.

Selenium deficiency has been diagnosed with increasing frequency in both chicken and turkey operations over the past five years. No natural feed ingredients have been found to contribute adequate levels of selenium to provide an economical solution to this nutrient deficiency which now has widespread geographic occurence.

Selenium deficiency has been diagnosed in commercial poultry flocks in which the assayed selenium content of the ration was above the reported nutritional requirement. This indicates an accentuation of the requirement under stress conditions or perhaps low availability of the selenium in natural ingredients. It is believed that marginal levels of selenium in feeds cause impaired performance of many poultry flocks in which no visible symptoms are observed.

Economic losses to poultry producers attributed to lack of approval for addition of inorganic selenium to feeds may originate from:

1. Mortality, reduced weight gains, impaired feed conversion, loss of egg production and other losses affecting quality of the birds to be marketed.
2. Higher feed ingredient costs to increase natural selenium levels.

The following assumptions and estimates of economic losses represent an apprasial by the scientific staff of a national feed manufacturer of the economic impact of selenium deficiency on the chicken and turkey industries.

Turkeys

Assumptions: The following calculations are based on 57.5 million turkeys being produced in 1972 in selenium deficient areas:

- 25% of turkeys are affected to the extent of showing 10% higher mortality to four weeks of age
- 5% less grade A turkeys in affected flocks showing mortality
- 50% of turkeys show impaired growth and feed conversion (5% on growth and 3% on feed conversion)
- Above losses in addition to increased ingredient costs of $1.00/ton in attempt to alleviate deficiencies.

Economic Losses:

Mortality:	0.25 x 57,500,000 x 0.10 = 1,437,500 mortalities @$0.80/turkey =	$1,150,000
Reduced Grade:	57,500,000 x 0.25 x 0.05 x 18 x $0.05 = (no. birds)(% affected)(%grade(Wt. (loss/ loss) birds) lb.)	$ 646,875
Impaired Growth & Feed Conversion	57,500,000 x 0.50 x 18 (av. wt.) = 517,500,000 lbx. turkey produced 5% loss of weight = 0.05 x 517,500,000 = 25,875,000 @ 23 cents/lb. =	$5,951,250
	3% loss in feed conversion - 0.03 x 517,500,000 x 3.3 (av. feed conv.) = 51,232,500 lbs. feed @ 4 cents/lb. =	$2,049,300
Added Feed Cost:	57,500,000 turkeys @ 60 lbs/bird = $\frac{3,450,000,000}{2,000}$ = 1,725,000 tons @ $1.00/ton =	$1,725,000
Total Annual Loss to Turkey Producers		$11,522,425

Broilers

Assumptions: The following calculations are based on 1.5 billion broilers being produced in 1972 in selenium deficient areas.

- 5% of broilers are affected to the extent of showing 3% higher mortality to four weeks of age
- 25% of broilers show impaired growth and feed conversion (3% on growth and 2% on feed conversion)
- Above losses in addition to increased ingredient costs of $1.00/ton in attempt to alleviate deficiencies

Economic Losses:

Mortality:	0.05 x 1,500,000,000 x 0.03 = 2,250,000 mortalities @ 0.30/bird =	$ 675,000
Impaired Growth & Feed Conversion:	1,500,000,000 x 0.25 x 3.7 = 1,387,500,-000 lbs broiler meat	
	3% loss of weight - 0.03 x 1,387,500,000 = 41,625,000 @ 15 cents/lb.=	$6,243,750
	2% loss in feed conversion - 0.02 x 1,387,500,000 x 2.2 (av. fd. conv.) = 61,050,000 lbs. feed @ 4.5 cents/lb =	$2,747,250
Added Feed Cost:	1.5 billion birds x 8 lbs/birds = $\frac{12,000,000,000 \text{ lbs.}}{2,000}$ - 6,000,000 tons @ $1.00 /ton =	$6,000,000
Total Annual Loss to Broiler Producers		$15,666,000

Pullets and Hens

Assumptions: The following calculations are based on 200,000,000 pullets and hens on feed in 1972 selenium deficient areas.

- 5% of replacement pullets are affected to the extent of showing 3% higher mortality to six weeks of age
- 10% of the laying hens show reduced egg production and impaired conversion (3% less eggs and 2% higher feed conversion.

- Above losses in addition to increased ingredient costs of \$1.00 per ton on 20% of feed for pullets and hens.

Economic Losses:

Mortality:	0.05 x 200,000,000 x 0.03 = 300,000 mortalities @ \$0.50/bird =	\$ 150,000
Impaired Egg Production & Feed Conversion:	0.10 x 200,000,000 = 20,000,000 hens affected 0.03 x 20 (dozen eggs/hen) = 0.6 dozen/hen 0.6 x 20,000,000 = 12,000,000 dozen @ \$0.30/dozen =	\$3,600,000
	20,000,000 hens x 20 dozen/hen x 4.0 lbs. fed/dozen = 1,600,000,000 lbs. feed x 0.02 = 32,000,000 lbs. @ 3.5 cents/lb.	\$1,120,000
Added Feed Cost:	0.20 x 200,000,000 x 100 lbs./bird = $\frac{4,000,000,000}{2,000}$ = 2,000,000 tons @ \$1.00 ton	\$2,000,000
Total Annual Loss to Pullet and Egg Producers		\$6,870,000

Summary - Economic losses in the poultry industry resulting from selenium deficiency are estimated at approximately \$34,000,000 annually, Fortification of feeds with an inorganic form of this essential nutrient could alleviate this economic burden at an annual ingredient cost of approximately \$250,000.

Table I

69 POULTRY PRODUCTION

	Laying Hens[1] Av. No. (000)	Broilers[1] No. Produced (000)	Turkeys[1] No. Produced (000)
Maine	5,831	72,900	14
New Hampshire	1,559	482	31
Vermont	588	18	8
Massachusetts	2,363	3,216	242
Connecticut	4,084	6,657	111
New York	10,487	2,438	412
New Jersey	4,139	950	111
Pennsylvania	14,720	48,998	1,925
Delaware	610	133,503	150
Maryland	1,600	174,274	95
Virginia	5,096	63,469	4,179
W. Virginia	1,482	16,542	676
Ohio	9,468	10,051	3,919
Indiana	12,812	13,934	3,621
Illinois	8,232	-	671
Michigan	6,188	777	882
Wisconsin	5,109	15,183	3,166
Kentucky	3,121	7,190	57
Tennessee	5,464	46,132	14
N. Carolina	15,342	280,637	9,408
S. Carolina	5,078	24,219	2,536
Georgia	24,705	442,221	1,633
Florida	11,066	38,737	1,572
Idaho	830	7,936	
Washington	4,422	21,436	573
Oregon	2,305	14,700	1,800
California	37,740	76,757	15,080
TOTAL	204,441	1,523,357	52,886
United States	313,343	2,788,195	106,204
% of Birds in States Listed	65%	55%	50%

1/ Figures from USDA *Agricultural Statistics* 1970

1/19/72

9. Analyze Whether the Proposed Action Is or Is Not Major and Whether It will Or Will Not Significantly Affect the Quality of the Human Environment:

The addition of supplemental selenium at nutritional levels to feeds for chickens, turkeys and swine is not a major action that will significantly affect the quality of the human environment.

Insignificant levels of selenium would be returned to the soil which would have no significant short or long term effects on the level of selenium in the environment.

10. If the Proposed Action is Major and Will Significantly Affect the Quality of the Human Environment, Analyze Whether the Benefit to the Public Will Outweigh the Risks to the Environment:

NOT APPLICABLE.

Lee H. Boyd, Director
Feed Control and Nutrition

July 26, 1972

SECTION IX - PROPOSED TOLERANCES

SUPPLEMENTAL FOOD ADDITIVE PETITION

Supplemental selenium for ruminant livestock, petition to amend 21 CFR 121.325 (573.920) LHB

ENVIRONMENTAL IMPACT ANALYSIS REPORT

Selenium For Ruminants Task Force
c/o American Feed Manufacturer's Association
1701 N. Fort Myers Drive
Arlington, Virginia 22209

August 26, 1976

ENVIRONMENTAL IMPACT ANALYSIS FOR THE ADDITION OF 0.1 PART PER MILLION OF SELENIUM TO THE DIETS OF BEEF CATTLE, SHEEP AND DAIRY CATTLE

Contents	Page

Contents	Page

ENVIRONMENTAL IMPACT ANALYSIS FOR THE ADDITION OF 0.1 PART PER MILLION OF SELENIUM TO THE DIETS OF BEEF CATTLE, SHEEP AND DAIRY CATTLE

1. Background and Description

1.1 Description of Proposed Action: Selenium is an essential trace nutrient for animals and probably for man which, like other trace nutrients, can be toxic if consumed in excessive amounts. The characteristic which distinguishes selenium from other trace nutrients is its relatively high degree of toxicity. Selenium is cited as one of the few mineral elements absorbed by plants in sufficient concentrations to kill animals that eat the plants. For this reason, it is necessary to consider the effect of selenium supplementation not only on the direct recipients (cattle and sheep) but also on its ultimate consumer, the human population.

For many years, there was concern over the toxic effects of selenium on animals; only more recently have the nutritional aspects of selenium become well recognized. Selenium is now accepted, after extensive research studies, as a necessity for the health and growth of large numbers of domestic animals and birds in widely diverse sections of the world. These studies demonstrated that dietary supplementation with selenium is effective in preventing the clinical signs of selenium deficiency in animals and birds.

Based on these studies, permission to add supplementary selenium to the diets of swine and poultry was granted by the Food and Drug Administration in February of 1974. This approval permits the addition of 0.1 ppm of supplemental selenium to the diets of broiler chickens and swine and 0.2 ppm to the diets of turkeys. Ruminant livestock (cattle and sheep) also suffer from selenium deficiencies (53% of the ruminant livestock produced in the United States is grown on feeds which are deficient in selenium). This represents an important loss of meat and milk to the American consumer.

The purpose of the proposed action is to permit the correction of dietary deficiencies of selenium in the diets of ruminant livestock through the addition of 0.1 ppm of selenium (as sodium selenite or sodium selenate).

Most of the information prepared in the final environmental impact statement which was submitted prior to approval of selenium as a food additive for inclusion in the diets of poultry and swine is also of importance in considering the addition of this essential nutrient to the diets of ruminant livestock.

1.2 Distribution of Selenium: Selenium occurs in nature mostly as mixed sulfides of lead, copper, mercury and silver. A number of measurements of the total selenium content of soils was made in connection with studies of toxicity in the western United States during the period 1933 to 1949. These studies have been reviewed by Lakin (1961). Soils containing as much as 100 ppm of total selenium have developed from Cretaceous sedimentary rocks in the Northern Plains and along the eastern front of the Rocky Mountains. The concentration of selenium in these soils is high variable; in a single field, soils containing more than 50 ppm of total selenium may be interspersed with soils containing less than 1 ppm.

The concentration of selenium in some seleniferous soils has been reduced both by leaching during the soil development processes and by irrigation water. Moxon et al. (1939) have estimated that over 80 percent of the selenium originally present in some Cretaceous sediments in South Dakota has been removed from the upper part of the section during the development of a soil profile. Lakin (1961) presented evidence that selenium is being removed from some irrigated areas in drainage waters. Kubota et al. (1967) observed that forage growing on the alluvial bottomlands along the Missouri and Mississippi Rivers contained more selenium than did forage growing on the adjacent upland soils. This may be interpreted as evidence that the Missouri and Mississippi Rivers are transporting selenium toward the sea from the upper parts of their watersheds. Even though selenium is being removed from the surface layers of the seleniferous areas of the United States, it has not been established that this removal is resulting in a significant decrease in the areas that are potentially capable of producing plants containing toxic concentrations of selenium.

A unique feature of the distribution of selenium in plants in the United States is the occurrence of several broad areas where almost all the plants sampled contained low levels of selenium. These areas coincide with areas where selenium deficiency in livestock and poultry has been most noticeable (Figure 1). A major area of selenium-deficient soil includes central and southern Florida and the tidewater section of the south Atlantic coast. Here the soils were formed by recent marine and coastal deposits.

These soil-forming materials were generally laid down long after the period of selenization of the Western Great Plains and the Rockies. The selenium content of the forages grown in these selenium-deficient areas varies from 0.01 to 0.10 ppm. Obviously, there are important differences in the concentrations of selenium in animal feeds produced in different areas. These are demonstrated in the work of Bruins et al. (1966), in which a standard turkey diet prepared from materials produced in western Iowa was compared with a similar diet prepared from materials produced in Ohio and New York. The Iowa diet contained 0.37 ppm of selenium, and turkeys fed this diet showed no evidence of selenium deficiency. The Ohio-New York diet contained 0.08 ppm of selenium and turkeys fed this diet showed a high incidence of gizzard myopathy (a muscle disease).

The median concentration of selenium produced in areas considered having adequate soil selenium was 0.26 ppm. Presumably, the concentration of selenium in feed grains would show a similar distribution.

1.3 Role of Selenium in Nutrition: Selenium is an essential trace nutrient which is needed by poultry and livestock to permit normal growth and metabolism. Although it is present in a wide variety of feedstuffs, the levels that occur are often not sufficient to satisfy the animal's metabolic requirement. Animal nutrition problems now recognized to be due to selenium deficiency have been suggested for over 30 years. Recognized instances of selenium deficiency diseases have unquestionably increased, but these may be due to improved diagnoses. The insufficiency precipitates clinical signs of debilitation in a significant portion of our food-animal population. Estimates of economic losses caused by selenium deficiency in beef cattle, dairy cattle and sheep are in the millions of dollars (see Appendix C).

Ample evidence is available to show that these losses could be prevented if selenium could be used to supplement ruminant livestock diets. This evidence demonstrates that the proposed use of selenium is necessary and safe to the animals treated and to humans consuming the food derived from these animals.

New interest in the biological significance of selenium has developed in recent years, although for many years there was concern over its toxic effects at high levels upon animals. Objections to the concept of selenium's essentiality as a nutrient continued to be raised, largely on the basis that some of the selenium-responsive diseases (diseases which can be prevented by selenium therapy) also responded to other dietary supplementation, notably vitamin E. In independent discoveries (Schwarz and Foltz, 1957; Patterson et al., 1957) selenium was identified as a third factor (vitamin E and cystine, a sulfur amino acid, had already been identified) active in preventing degeneration of the liver in rats and was shown to prevent exudative diathesis (a disease characterized by edema and subcutaneous capillary hemorrhages) in chicks fed torula yeast low in vitamin E. These discoveries led to investigations with other species of animals.

The existence of certain metabolic problems among ruminant animals that are responsive to small amounts of selenium has been recognized for a number of years. In 1958 research teams at Oregon State and Cornell Universities documented that white muscle disease, a myopathy of young ruminants, could be prevented by the addition of 0.1 ppm Se to causative diets (Muth, et al., 1958; Hogue, 1958). Subsequently, extensive studies of forages and other plant feedstuffs (Kubota, et al., 1967) have revealed broad areas in the United States where almost all of the plants sampled showed low levels of selenium, and it has been noted that these areas coincide with those where selenium deficiency in livestock and poultry has been most serious (NAS-NRC, 1971).

There has been a definite increase in recognized incidence of Se-responsive disease in ruminant animals in this country since 1958, some of which probably relates to improved diagnostic methods. There are some indications, however, that depletion of topsoil reserves of Se may have occurred, especially where irrigation and intensive cropping have been applied to previously marginally-productive lands, and that these may have extended the scope of Se-deficiency problems with livestock. In some cases, use of competing elements such as sulphur in fertilizers or soil amendments has limited the uptake of available Se by plants. Also, changes in livestock management practices including a shift to birth of calves and lambs in winter months when low dietary levels of vitamin E place added importance on availability of dietary Se, may have led to increases in occurrence of white-muscle and other Se-responsive diseases in young ruminants (NAS-NRC, 1971).

Other evidence of beneficial effects of Se in diets for ruminants has been documented. It has been shown, for example, that sub-optimal growth of lambs can be improved in some areas when supplementary Se in made available. Oregon experiments showed that prepartum administration of Se to ewes increased post-natal weight gains of their lambs (Oldfield, et al., 1960) and similar experiences have been recorded elsewhere, e.g. in New Zealand (Jolly, 1960) and Scotland (Blaxter, 1962). The latter reference summarized comprehensive trials involving 4,448 lambs on 76 farms and showed that Se-treated lambs gained an average of 0.81 lb. more than untreated ones over a 3-4 month period.

Burroughs et al., (1963) showed in Iowa cattle feeding trials that addition of 0.05 - 0.10 ppm to high concentrate rations for cattle resulted in significantly greater weight gains over a 141-day period. In New Zealand, Hartley (1961) showed that growth of forage-fed beef calves given Se was increased by 50% over that of control calves that did not receive the supplement.

Selenium apparently is also required for normal reproductive processes in ruminant animals. Hartley and Grant (1961) in New Zealand demonstrated that dosing ewes on ranches where abnormally low lambing percentages had occurred with 5 mg Se as Na_2SeO_3 at monthly intervals improved their reproductive performance from 62% (lambs/100 ewes) to 94%. Later research in this country showed that Se was also important to normal reproduction in the male, and that specific defects occurred in the morphology of sperm from Se-deficient male laboratory animals (Wu, et al., 1969). In cattle, it has been shown that Se-therapy superimposed on a Se-deficient diet situation, has been helpful, along with vitamin

E, in reducing incidence of retained placentas (Trinder et al., 1969). This finding has been recently confirmed by Julien and Conrad, 1976, in which the incidence of retained placentas was reduced from 40 - 50 percent to 8 - 12 percent by injecting dairy cows with 50 mg of sodium selenite 20 days before calving.

As the widespread incidence of Se deficiency in livestock has been appreciated, other instances of beneficial responses to Se supplementation of animals have occurred. Considerable use of veterinary prescribed Se in cases of diarrhea or scours in young calves and lambs has taken place, with apparently successful results (Kendall et al., 1960; Smithcors, 1962; and Wolf et al., 1963).

These studies relating specifically to ruminant species are part of a very much larger scientific literature relating to many animal species, that has developed over the last two decades, the aggregate result of which has been the recognition, by authoritative sources, of the essential status of Se as a micronutrient.

The need for an adequate level of selenium in the diets of all types of domestic livestock and poultry is, therefore, well recognized.

The dietary requirements and ppm of selenium toxic for domestic animals as summarized by the National Research Council are in Table 1. Values for swine and poultry are presented in addition to those for ruminants for comparative purposes. Whether the animal is a ruminant or nonruminant, it generally is considered that its selenium requirement will be satisfied by .1 ppm of the element in the diet. A higher .2 ppm, however, has been established as the requirement for turkeys. Interpretation of available data has resulted in wide ranges for toxic amounts of selenium for certain species. Even so, the widest range of 3 to 20 ppm set for sheep yields a minimum toxic-to-required ratio of 30, indicating a greater margin of safety with selenium than occurs with copper, for example.

Table 1. Dietary Requirements and toxic levels of selenium for domestic animals.

		Selenium (ppm)	
Species	Reference	Requirement	Toxic
Dairy Cattle	NRC, 1971	.1	5
Beef Cattle	NRC, 1970	.05 to .1	-
Sheep	NRC, 1974	.1	3 to 20
Swine	NRC, 1973	.1	5 to 10
Chickens (0 to 8 wk)	NRC, 1971	.1	10
Turkeys (0 to 8 wk)	NRC, 1971	.2	-

2. Probable Impact on the Environment

2.1 Primary Environmental Impact: Primary environmental impacts can result from the direct application of foreign substances to the environment. In the case of selenium, which is widely distributed in nature and will be administered via the feed to animals at low levels, no primary environmental impact resulting from its use is anticipated.

2.2 Secondary Environmental Impact: A variety of secondary environmental effects would occur. Beneficial impacts would accrue with regard to land use since selenium supplementation would permit the more efficient production of poultry and livestock. This enhanced productivity allows a more efficient utilization of the acreage allocated for food production and also of allied agricultural inputs (fertilizer, seed, pesticides and labor).

In order to determine the potential adverse environmental effects of the proposed action, the following factors were given consideration:

1. Toxicology

a. Animal

Selenium in the form of sodium selenite (Na_2SeO_3) or sodium selenate (Na_2SeO_4) is highly toxic. Consumption of plant materials containing 400-800 ppm of selenium have been fatal to sheep, hogs, and calves. Chronic selenium toxicity in livestock occurs when animals consume seleniferous plants containing 3-20 ppm of selenium over a prolonged period. Miller and Schoening (1938) reported that selenium as sodium selenite was toxic for swine when fed at the rate of 11.3 ppm.

In studying the effect of selenium as sodium selenite in the ration of poultry, Moxon (1937) found evidence of toxicity when hens were fed 26 ppm; pullets, 6.5 ppm; and growing chicks, 8 ppm. While many factors enter into selenium toxication, the following factors revealed by Muth and Binns (1964) appear to be the most important: (1) size and frequency of the doses; (2) characteristics of the compound; (3) presence of combining, reducing, diluting, or synergistic substances; (4) inherent susceptability of the animal;

and (5) efficiency of elimination after absorption. The statement by Trelease and Beath (1949) that "It is not yet possible to state with any degree of accuracy what constitutes the minimum toxic dose of selenium in each of its forms for different kinds of livestock," is still a pertinent one. It is most difficult to state with any degree of accuracy what actually constitutes the minimum toxic dose of selenium in each of its numerous forms for different species of livestock or for man. The ratio between beneficial dose and toxic dose, based on Factor-3 selenium, is of the order of 1:100.

A variety of toxic effects are noted when excessive quantities of selenium are ingested by livestock and poultry. Generally, these animals will suffer from a loss of appetite, atrophy of the heart, cirrhosis of the liver and anemia. A more complete description of the toxic effects of selenium can be found in "Trace Elements in Human and Animal Nutrition," by E. J. Underwood (1971).

It has been well-documented that the minimum toxic level of selenium in poultry and swine feeds approximates 3.0 ppm. Feeds that have been supplemented with 0.1 or 0.2 ppm of selenium contain an amount of selenium which is well below that which is toxic to poultry and swine. Accordingly, such feeds are safe for poultry and swine.

b. Human

The addition of selenium to animal feed has been thoroughly considered because of the questions that have been raised concerning the possible carcinogenic (cancer causing) activity of selenium.

Available animal data which have been extrapolated to effects on humans have been evaluated by the Food and Drug Administration and the National Cancer Institute. These data can be summarized as follows:

(1) Nelson et al. (1943)

Selenium was initially thought to be carcinogenic on the basis of studies performed by these workers. The studies were designed to compare the toxicity of graded levels of naturally occurring selenium with that caused by potassium ammonium sulfoselenide (Selocide--a systemic insecticide). Female rats were reared on a low protein diet (12 percent) which contained 5, 7 and 10 ppm of selenium from natural sources and 10 ppm of selenium from ammonium potassium sulfoselenide for a lifetime. Mortality was high and found to be approximately proportional to the level of dietary selenium. One hundred and twenty-six rats were divided into 7 groups of 18. Only 53 survived 18 months; 39 survived 24 months. Of the 53 rats that survived 18 months, 11 developed liver tumors and 4 developed advanced adenomatoid hyperplasia (benign tumor). None of the tumors metastasized. It is believed that the neoplastic lesions (new or abnormal growth) observed in this study were secondary to the cirrhosis promoted by the nutritionally inadequate diets that were used.

(2) Klug and Hendrick (1954)

Groups of 35 male rats were treated for a lifetime with up to 19 ppm of selenium derived from organic sources. The selenium treatments resulted in decreased life spans and liver damage. No liver tumors were evident.

(3) Volgarev and Tscherkes (1967)

Studies which appeared to confirm the results of Nelson et al. (1943) were conducted by these workers. These studies tested the effects of selenium (as sodium selenate) in male rats at levels ranging from 4.3 to 8.6 ppm. The diets used contained 12 percent protein. The first study resulted in tumor development in 14 of 40 animals. In the second, 5 of 40 animals developed tumors. In the third study involving 100 animals, no animals developed tumors. No control animals were used in these studies and it was subsequently discovered that the rats used in the first 2 studies were infested with a parasite which is known to induce tumors.

(4) Tinsley et al. (1967) and Harr et al. (1967)

These authors conducted an extensive study of chronic selenium toxicity in rats to determine whether excess selenium produces liver cancer. A total of 1,437 rats was used with 274 of this total serving as controls. Three diets were tested (12 percent casein, 22 percent casein, and a commercially available rat chow). Selenium treatments ranged from 0.5 to 16.0 ppm and N-2-fluorenyl-acetamide (a known carcinogen) was used as a positive control. Of the 1,126 animals that were autopsied, 63 neoplasms were found; 43 of these occurred in the 90 rats receiving N-2-fluorenyl-acetamide. The other 20 neoplasms were randomly distributed throughout the rats receiving the various experimental diets. No hepatic neoplasms were found in the rats fed selenium.

(5) Schroeder and Mitchener (1971)

Male and female rats in groups of 50 were treated with sodium selenate and/or sodium selenite (3 ppm of selenium) via the drinking water. Because of the high toxicity of the sodium selenite treatment, the animals were switched from this treatment, after the first year, to sodium selenate at the same dose. All of the surviving rats were treated for 2 years. There were no tumors observed in the rats started on sodium selenite and switched to sodium selenate. For the groups treated with sodium selenate for the lifetime, however, it was claimed that a higher incidence of tumors were found. Critical analysis of these studies was not possible since the sodium selenate-treated rats lived longer than the control animals. Thus one could not attribute the tumors to sodium selenate or the increased life span.

(6) Schroeder and Mitchener (1972)

These same authors repeated the rat studies in mice. Here, treatment with 3 ppm of selenium via the drinking water did not have a significant effect on the incidence of spontaneous tumors.

These studies, examined in total, permit the conclusion that selenium at nutritionally required levels is not a carcinogen. Available evidence at higher levels is inconclusive.

Selenium at high dietary levels (above 2 ppm) is a proven hepatotoxic agent. Early studies at dietary levels of 5, 7 and 10 ppm showed liver damage and regeneration in rats and increased incidence of hepatoma in treated animals as compared with controls. Hepatoma did not occur in the absence of severe hepatotoxic phenomena. In more recent studies, hepatotoxicity was observed in rats fed selenium at 2 ppm. At 16 ppm, more severe liver damage was observed but was not associated with hepatoma. No hepatotoxic effects were noted at 0.5 ppm or below.

Knowledge of selenium residue distribution and concentration levels in food animal tissues is important in order to assess the potential for human toxic effects. Limited data on the distribution of selenium in animals and birds have been available for some time as a result of analyses conducted in connection with studies of selenium toxicity and selenium deficiency. Moxon and Rhian (1943) reported 5.6 ppm of selenium in the liver and 3.0 ppm in the muscle of steers that had been maintained on seleniferous rangeland for 3 years. Maag and Glenn (1967) fed sodium selenite to steers until six out of eight animals died from selenium poisoning. The level fed was 12-24 mg./kg. of body weight per week. The selenium content of the muscles of these steers ranged from 0.10 to 0.73 ppm. The liver contained 5.0-12.3 ppm of selenium.

Useful reviews of levels of selenium that occur under normal physiological conditions have been provided by Ganther (1965) and by Hartley (1967). It has been shown that animals rapidly excrete much of the administered selenium.

Scott and Cantor (1971) have shown, using graded levels of sodium selenite in diets for chickens and turkeys, that the selenium content of blood, muscle, and liver tends to plateau as the selenium content of the diet is increased. After selenium had been added to the diet at the rate of 0.2 ppm, the selenium content of blood was 0.2 ppm in chicks and 0.12 ppm in turkey poults. The selenium content of the liver was somewhat higher--about 0.6-0.7 ppm for both chicks and poults. These selenium levels are well within the range found in chickens and turkeys receiving normal rations. Levels of dietary selenium up to 0.67 ppm did not appreciably increase the selenium content of the blood, muscle, or liver of chicks or poults above the levels obtained with 0.2 ppm of dietary selenium in the form of sodium selenite.

The retention of dietary selenium and its distribution in various tissues of the animal have been studied intensively through the use of oral selenium. More recent studies utilizing lambs as test animals indicate that 25-75 percent of an oral dose of selenium is excreted within a few days after intake (Ehlig et al., 1967; Ewan et al., 1968 a and b). Ruminants tend to excrete more of the dietary selenium in the feces than do nonruminants. Animals that have been depleted of selenium retain a higher percentage of an oral dose of this element than do animals that have been on a selenium adequate diet before dosing. Only minor effects of vitamin E on retention and distribution of selenium have been noted.

Information is meager concerning the potential toxicity of selenium in human diets in the United States. Such information has been collected and summarized by Frost (1972), Trelease and

Beath (1949), Rosenfeld and Beath (1964), Smith and Westfall (1937), Hadjimarkos (1965), and Williams et al. (1941). Thus, Smith and Westfall (1937) conducted a survey of the relationship between the selenium content of urine and of food in 14 rural families living in the seleniferous area of the U. S. (South Dakota and Nebraska). The selenium concentration in the urine of this group of families ranged from 0.20 to 1.98 ppm. Another survey (Sterner and Lidfeldt, 1941) involving the urine of 60 male industrial workers living in a "low" selenium area (Rochester, New York) revealed that the urine selenium concentration varied from 0.001 to 0.025 ppm of selenium. The significance of these low levels of selenium excreted is difficult to assess. There is no evidence that any people in the U. S. are suffering from toxic levels of selenium in food. Several investigators have provided evidence that elevated dietary selenium levels may contribute to increases in dental caries (Hadjimarkos, 1965; Ludwig and Bibby, 1969; Buttner, 1963). Public Health officials have taken action on the bases of reports that selenium may contribute to dental caries, on reports that the element is a potential carcinogen, and that concentrations of selenium in water considered safe for man were found toxic for fish. Their action took the form of lowering the previously permitted level of selenium in water from 0.05 ppm to 0.01 ppm (Public Health Service Publication 956, 1962). The effects of the proposed action on this permissible selenium level in water are discussed (pages 20 - 25).

It has been shown, however, that use of feeds containing selenium at certain low levels (in some cases including those levels set forth in the regulation) does not result in an increase to toxic levels in the selenium concentration of the edible products of sheep and beef cattle (Appendix A, Tables 3 and 4). Thus, the animals tested absorbed dietary selenium in proportion to their physiological needs. Excesses are rapidly excreted.

c. Wildlife

The toxic effects of selenium on aquatic biota have been reviewed by Rosenfeld and Beath (1964). Freshwater catfish died within 48 hours after receiving intraperitoneal injections of 0.15 mg. or more of selenium as sodium selenite. Injections of 0.05 mg. of selenium resulted in death after 12 to 15 days. Edema and a disturbance in the hematopoetic system (blood forming) were observed. Ten ppm of selenium in the water is lethal to carp in 25 days and mudsnails in 8 days. It is also acknowledged that 2.5 ppm of selenium in the water is toxic to Daphnia, a small test animal known to be highly susceptible to toxic substances.

Duck sickness was produced by the addition of 20 ppm of selenium to the drinking water. Many of the symptoms were identical with those of Clostridium botulism--type C.

2. Rate of uptake by the biota and potential for food chain concentration (biomagnification).

The fact that certain substances (particularly pesticides and radionuclides) become concentrated at the higher food chain levels has been well-documented. One study by Metcalf et al. (1971) utilizing a model ecosystem, has shown that radiolabeled DDT was accumulated in mosquito larvae, snails, and fish as DDE, DDD, and DDT, and concentrated from 10,000 to 100,000-fold.

In the case of selenium, it is well-known that certain native plants growing on seleniferous soils accumulate high concentrations of this substance (Rosenfeld and Beath, 1964). In certain locations, accumulator species containing over 1,000 ppm of selenium have been found growing alongside grasses containing less than 10 ppm (Appendix A, Table 7). These so-called selenium accumulator plants include 24 species and varieties of *Astragalus* (milk vetch); section *Xylorhiza* (woody aster) of *Machaeranthera*; section *Oonopsis* (goldenweed) of *Haplopappus*; and *Stanleya* (prince's plume). The accumulator plants generally grow in dry, nonagricultural areas, and range animals do not graze them unless forced to by a shortage of other feeds. The geographical distribution of certain species of *Astragalus* is presented in Appendix A, Table 6.

Information with regard to the wildlife which feed on selenium accumulator plants is unavailable. Since these are noxious weeds which contain high levels of selenium, it is unlikely that these plants would be preferred as a feed source for the indigenous fauna. Probably, the toxicity of selenium to wild herbivores would be of the same order of magnitude as that observed in domestic livestock and poultry. FDA can only speculate that predators will not be adversely affected.

There is a paucity of information on the potential concentration of selenium in aquatic food chains. However, studies by Sandholm et al. (1973) showed that the phytoplankton, Scenedesmus dimorphus actively concentrated radiolabeled selonomethionine, but neither actively nor passively concentrated inorganic selenite. It was concluded that common water plants do not accumulate large quantities of selenium from surrounding water. These authors also observed that zooplankton (primarily Daphnia pulex) absorbed selenium from selenite. Fish concentrated only a small amount of organic or inorganic selenium directly from water, but did concentrate it from food. Thus, biomagnification by flora and fauna is possible and should be considered in determining potential environmental impacts. With reference to the proposed action, however, the major concern is directed towards assessing the changes in biomagnification potential caused by the small increment of selenium that will be distributed into the environment. Provided this increment is small enough, currently operative natural biomagnification schemes would be unaltered.

3. Rate of input into the environment.

In order to determine whether or not probable secondary impacts will occur, it is necessary to estimate the rate of input of selenium into the environment. This estimate is based on an analysis which assumes that all of the selenium administered to the animals will be excreted. It further assumes that excreta will be disposed of by soil application at the rate of 5 tons of waste dry matter per acre. This is the highest practical rate of application.

HYPOTHESIS 1. None of the selenium leaches from the soil.

The highest level of supplemental selenium permitted on a practical basis by this petition would be 0.1 ppm. If all of this were passed into the waste with 40 percent of the dietary matter excreted, the level of selenium in the waste from 0.1 ppm added selenium would be 0.25 ppm selenium on a dry weight basis. Converted to a ton basis, a ton of dry cattle waste would contain 0.2773 grams selenium from the added selenium. The application of 5 tons of dry cattle waste per acre would add only 1.136 grams selenium per acre.

In the normal farming practices, the waste would be worked into the top 6 inches of soil. The top 6 inches of soil per acre weighs 2,000,000 pounds (M. L. Jackson, 1958) or 909,000 kilograms. Therefore, a 1.13 grams increase in selenium per 909,000 kilograms is equivalent to an increase in selenium content of 0.0012 ppm from the 5 tons of cattle waste. Single application of 900 grams selenium per acre from sodium selenite have been added without detrimental effects to sheep fed forages grown on the treated soil (in Selenium in Nutrition, 1971). Sheep are known to be among the most sensitive animals to selenium. Stated another way, the annual addition of 2.27 grams selenium per acre would require 396 years to equal the 900 grams per acre selenium addition referred to above, assuming that all the selenium is accumulated in the top 6 inches of soil.

In general, farmers apply the waste to the soil at the time of plowing in either spring or fall. As such, as much as one year's production of waste may be stored in piles. It has been shown

(Viets, 1972) that up to 10 percent of the mineral matter in feedlot waste can be leached by rainfall. As such, each 1,000 ton pile of waste would lose 45.45 grams of selenium via the water runoff. If the selenium is absorbed by the surrounding one acre of soil, then the selenium concentration of this soil will increase by 0.05 ppm per year. This increase is negligible.

If, however, the selenium in the 1,000 ton pile of waste is totally leached by 24 inches of rainfall (2,467,051 kg.), then the water runoff would have a selenium concentration of 0.018 ppm. The contribution of this leached selenium to the concentration of selenium in the surface and subsurface streams is difficult to estimate since it would depend upon size, drainage area and rate of flow of these streams.

Since soils in many areas of the U. S. are deficient in selenium, and since the waste is applied to the soil in the area in which the animals are grown, the effect, if any, of the addition of the small amounts of selenium would be beneficial to the animal consuming the forages and grains grown on these soils.

HYPOTHESIS 2. <u>All of the selenium leaches from the soil and finds its way into the waterways</u>.

The area of the U. S. which will require selenium supplementation due to deficient levels in grains and feedstuffs comprises the eastern U. S. and west coast area of Calfiornia, Oregon and Washington (Figure 1). The eastern U. S. is defined as the area east of the western borders of the following states: Minnesota, Iowa, Missouri, Arkansas and Louisiana. Of the states in the above described deficient areas, California has the lowest mean annual rainfall of 24 inches (Miller, 1973). For the purposes of this discussion, we are also assuming the addition of 5 tons of dry manure per acre contributing the same levels of selenium per acre referred to above (i.e., 1.136 grams from cattle and sheep waste). Twenty-four inches of rainfall would be equivalent to 2,467,051 kilograms water per acre. Therefore, if the amount of selenium added by 5 tons of dry cattle waste (1.136 grams) is assumed to be totally leached out of the soil by the 24 inches of rainfall (2,467,051 kilograms) this would give a selenium concentration of 0.00046 ppm in the water.

There is an insufficient quantity of waste produced by all cattle and sheep in the eastern U. S. and Pacific coast areas to apply 5 tons to each acre of land in farms. The total waste production in cattle and sheep in the eastern U. S. and Pacific coast area is given in Appendix A, Table 1. The total waste produced annually would be 82,232,000 tons for beef cattle and 55,901,000 tons of dairy waste and 732,562 tons of sheep waste. If this were spread at a rate of 5 tons per acre, then the beef waste would cover 16,446,400 acres or 16.1 percent of the land in farms in the eastern U. S. and Pacific coast regions (509,815,551 acres) (U. S. Census of Agriculture, 1964). The number of acres to which dairy and sheep waste could be added at the rate of 5 tons per acre is 4,448,641 acres or 11.1 percent of the land in farms.

The animal population in the acres in which selenium supplementation is required is given by species in Appendix A, Table 2 with the level of selenium which would be consumed at the proposed added selenium levels of 0.1 ppm for beef cattle, dairy cattle and sheep. The combined total selenium consumption for all species grown in the eastern U. S. and Pacific coast areas is 16,821,563 grams. Assuming all of the animals in these areas were given supplemental selenium, this would be the total possible selenium which could be added back to the land through the wastes.

If the total amount of possible selenium present in the waste (16,821,563 grams) is spread over the entire land area in farms (509,815,551 acres) in the same area of the U. S., the amount of selenium added per acre per year should not exceed 0.0329 grams. This would add 0.000034 ppm selenium to the top 6 inches of soil.

The earth's crust is calculated to contain 0.09 ppm selenium (Mitchell, 1964). The addition of 0.000034 ppm selenium to the soil through the waste from the supplementation of ruminant rations would amount to only 0.0384 percent of the selenium present in the earth's crust for that area.

Soils in areas where selenium deficiency diseases occur are reported to contain 0.04 ppm selenium or less and areas of moderate selenium content where selenium deficiency diseases do not occur contain 0.5 ppm to 5.0 ppm (Allaway, 1968). The addition of 0.000034 ppm selenium to soil containing low selenium levels (0.04 ppm) would only increase the selenium content 0.08 percent.

Adding 0.000034 ppm to the soils containing the lower limit of selenium for moderate selenium content soils (0.5 ppm) would increase the selenium content 0.0068 percent.

The maximum effect on the water as a result of total leaching out of the selenium from the waste by an annual rainfall of 24 inches would be insignificant. We have used 24 inches rainfall because this is the lowest mean annual rainfall of any state (Figure 2) in which supplementation is necessary (Miller, 1973). Other states have higher annual rainfall. Using 2,457,051 kilograms water per acre from the 24 inches of rainfall and 0.0329 grams selenium added per acre on farmland, the water concentration of selenium would be 0.0000132 ppm. The average concentration of selenium for the waters of the entire area would be lower than this since the average rainfall is greater than 24 inches annually and would be further diluted with water from land which is not in farms.

The United States Public Health Service has established 0.01 ppm selenium as a safe upper limit for human water supplies (Public Health Service Publication 956). The selenium content of seawater has been calculated to be 0.00009 ppm based upon analytical results from the Atlantic, Pacific, and Antarctic Oceans, Long Island Sound and the Carribbean (Schutz and Turekian, 1965). This indicates that the maximum level of selenium leached out of the soil from returning waste containing added selenium from sodium selenite or sodium selenate would be insignificant. It would be safe for both humans and aquatic life even at the maximum possible levels.

2.3 Conclusion: Compounds of selenium are, without question, highly toxic. The amounts required to satisfy essential nutritional requirements are between one-tenth and one-hundredth the minimum toxic levels for animals. Their use as feed additives should be carefully controlled to prevent harm either to the animals or to prevent excess selenium deposition in edible tissues destined for human food. No adverse environmental effects are anticipated when animal waste containing selenium is applied to the soil at a rate of 5 tons or less per acre. Under these circumstances, the amount of selenium added to the soil is so small that it is unlikely that natural biomagnification schemes in terrestrial and aquatic ecosystems would be adversely affected. Special precautions should be taken in those instances where animal waste is stored in piles to ensure that selenium leached by rainfall will not have direct access to the water table or other aquatic sources. The proposed use of sodium selenite or sodium selenate would assure that the nutritional requirements of poultry and swine are satisfied and present no hazard of increased selenium levels in human food above that found in tissues of normal animals.

3. Adverse Environmental Impact Considerations

Selenium is a natural component of the environment. In this regard, any adverse impact must be assessed in terms of the added burden the proposed use of selenium will place onto the ecosphere. Section IV demonstrates that this burden would be negligible and could be handled by acceptable safeguards.

Adverse environmental impact in the form of increased selenium levels in the soil and water supply may occur if animal feeds are over-formulated by the addition of excess selenium or addition of selenium to feeds high in selenium. However, the levels of selenium in animal tissues would most likely be unaffected by such over-formulation and excessive addition with the exception of possible increased levels in liver and kidney of treated animals (see Appendix A, Tables 3 and 4). At any rate, any such adverse environmental effects would not forseeably compromise human safety. Animal safety would be unaffected under controlled conditions since the margin of safety is adequate under such conditions.

To control these potential adverse environmental effects, the regulation stipulates that no more than one pound of a premix containing a maximum of 90.8 mg. of selenium per pound may be added to a ton of cattle or sheep feed. At this rate, 30 pounds of this premix would have to be added to a ton of feed to reach a toxic selenium level, a practice which is not expected to occur.

4. Alternatives to the Proposed Action

The alternative of not permitting the use of selenium would force livestock producers to rely on selenium obtained from natural sources. This alternative was rejected since natural sources (feedstuffs and drinking water) often contain less than the needed amount of selenium (Table 5).

The only method for mitigating a selenium deficiency in poultry and livestock requires the direct administration of selenium to the deficient animals. Two major problems are particularly pertinent in evaluating the feed route as a means of administering physiologically effective quantities of selenium. First, the amounts required are so small (less than 1 ppm in the diet dry matter) that there is a highly practical problem of adequate mixing with the large mass of feed material. Secondly, it may be difficult to avoid toxic levels of selenium by the addition of the nutrient to feeds under conditions currently applied in commercial agricultural practice. These problems should be considered in any program of direct addition of selenium to animal feed.

There are several ways in which direct selenium administration can be accomplished.

1. Soil Amendment

Selenium can be added to the soil on which our basic feedstuffs are grown. This practice has been successful in New Zealand where farmers have applied 14-28g of selenium (as sodium selenite) per acre. Since the selenium-deficient arable area of the U. S. encompasses in excess of 509 million acres, this technique of selenium treatment would require the distribution of at least 7 million kilograms of selenium. The proposed dietary use of selenium would involve only approximately 6 thousand kilograms, therefore, from an environmental standpoint, the dietary use is more desirable. In addition, we have a regulatory concern with soil amendment <u>via</u> fertilization. At present this route of administration is impossible to control.

2. Interregional Feed Blending

It is known that certain areas of the country produce basal feedstuffs which contain quantities of selenium at or above the required levels. It may be possible to use these feedstuffs as selenium sources. We discounted this alternative since it is well known that selenium from natural sources is not as biologically available as that from sodium selenite or selenate. In this regard, a feedstuff may contain "adequate" levels of selenium, but it could produce a selenium deficiency. Also, there would be insufficient quantities of "high" selenium ingredients to adequately balance "low" selenium ingredients. Interregional feed blending suffers from the further disadvantage that the high selenium commodities would have to be segregated in the marketplace. This practice is currently not feasible. The cost of transporting bulky feed ingredients would be expensive and would offset much of the intended economic benefit. In addition, the transportation of grain would require a considerable increase in energy consumption.

3. Corporeal Injection

This process would involve injecting animals with therapeutic levels of selenium. Its disadvantages accrue from the fact that each animal would have to be handled at periodic intervals. The current high density livestock production practices make this a costly and undesirable alternative.

4. Drinking Water Administration

This alternative is a variant of the feed method. Essentially similar quantities of selenium would have to be used. We discounted this alternative since livestock producers, in general, lack the metering devices necessary to assure that the animal will consume the required selenium dosage. Further, since water consumption is highly variable and dependent on climatic conditions, we doubt if the selenium dosage could be controlled with any degree of assurance.

5. Feed Monitoring

This alternative would provide for the establishment of a program for monitoring the levels of selenium in the animal's diet through extensive and frequent chemical or physical analyses. Such a program does not exist, but analytical methods that would be required for it are available. There are several acceptable methods published in the Journal of the Association of Official Analytical Chemists (A.O.A.C). Several new methods have been developed, including x-ray fluorescence spectrometry for the detection of potentially toxic levels of selenium and procedures for determining selenium in biological materials by neutron activation analysis.

Variations of this program would require individual feedmills to analyze either each ton of feed or each lot of feed ingredients prior to the addition of selenium. If each ton of feed were analyzed (analysis costs $15-20 per sample), the program would cost from a minimum of 70-100 million dollars (at least 9 million tons of feed affected), a sum which may exceed the potential benefit.

4.1 Conclusion: Of the six alternative methods proposed for satisfying the selenium requirements of swine and poultry, three (feed administration, corporeal injection, and drinking water administration) would involve the environmental distribution and use of about the same quantity of selenium. Rejection, therefore, of two of these alternatives (corporeal injection and drinking water administration) was based on feasibility and cost considerations. An additional alternative (feed monitoring) which could potentially limit selenium distribution was rejected for excessive costs. The alternative of soil amendment was rejected since its application would require the use of at least 1400 times more selenium than that required by feed administration. The alternative of interregional feed blending was attractive from an environmental viewpoint since no synthetic selenium salts would have to be distributed into the environment. It was thought, however, that the energy output required to accomplish the massive movement of feedstuffs coupled with cost and feasibility considerations would outweigh the proposed environmental benefits.

5. Relationship Between Local Short-Term Uses of Man's Environment and the Maintenance and Enhancement of Long-Term Productivity

There would be no known long-term detrimental effects on the environment of supplementing animal rations with selenium due to the very low level of addition to the soil of selenium from manure. Assuming, as discussed in Section IV, the application of 0.000034 ppm annually, it would take:

A. 25 years to change the selenium content of the farmland in the affected area by 1% when soil contains 0.09 ppm selenium.

B. 11 years for a 1% change in low selenium soils containing 0.04 ppm.

C. 144 years for a 1% change in soils containing moderate selenium levels (0.5 ppm).

The long-term beneficial effects can be more readily postulated since the selenium will be added to rations in areas where soils are deficient. The addition of selenium to these soils would help to minimize soil depletion occurring through intensive farming and natural leaching of selenium from the soil. The incidence of diagnoses of selenium deficiency diseases has progressively increased in poultry and swine.

For the short term, the various beneficial effects would accrue by rectifying the selenium deficiency. No short-term compromise of man's environment is foreseen.

6. Irreversible and Irretrievable Commitments of Resources Which Would Be Involved in the Proposed Action Should it be Implemented

Based on the usage level of this feed additive, there would be no known irreversible or irretrievable commitment of natural resources.

Selenium is obtained from mined ore as a by-product of the copper smelting process. The use of selenium salts in animal feeds further distributes the selenium and eventually returns it to the earth's crust, as discussed in Section IV. The amount of selenium added to the soil (as animal waste) or to stream and ground water (as selenium is subsequently leached from the soil) would not exceed that of the natural selenium present in the soil or water of areas in the United States where selenium is present at normal levels.

SECTION 7

APPENDICES

APPENDIX A

TABLES

Table # 1

ANNUAL RUMINANT WASTE PRODUCTION IN THE EASTERN U. S.[1] AND PACIFIC COAST AREAS BY SPECIES

Species	Lbs. of Feed Per Animal	Number of Animals Annually 1,000's	Total Pounds of Feed Consumed 1,000's	Total Lbs. of Dry Waste Produced 1,000's	Total Tons of Waste Annually
Beef Cow Replacement	5,400	4,666	25,196,400	16,519,973	8,259,986
Beef Cows	6,120	22,009	134,695,080	77,922,864	38,961,432
Dairy Cow Replacement	5,400	3,555	19,197,000	17,257,747	8,628,874
Dairy Cows	8,640	9,690	83,721,600	47,040,105	23,520,052
Steers, 500 lbs. and over	5,400	8,414	45,435,600	29,789,767	14,894,883
Bulls, 500 lbs. and over	5,400	1,579	8,526,600	5,590,450	2,795,225
Steers, Heifers and Bulls under 500 lbs.	2,520	19.591	49,369,320	82,153,470	41,076,734
Total Cattle Manure	38,880	69,504	366,141,600	276,270,000	138,135,000
Stock Sheep	1,088	3,308	3,598,560	1,243,643	621,821
Lambs	1,316	592	778,809	222,562	111,282
Total Ruminant Livestock	41,284	73,404	370,518,969	277,735,000	138,868,000

1) Includes all states east of the western borders of Minnesota, Arkansas, Louisiana plus California and Oregon.

2) Based on data published in USDA Agricultural Statistics 1975.

Table # 2

ANNUAL CONSUMPTION OF ADDED SELENIUM AT PROPOSED ADDED LEVELS
BY SPECIES FOR THE EASTERN U. S.[1] AND PACIFIC COAST AREAS

Species	Feed Consumed Per Animal	Number of Animals In Area	Supplemental Se Level	Total Selenium Consumed
	lbs.	1000's	ppm	gm
Beef Cow Replacement	5,400	4,666	0.1	1,143,917
Beef Cows	6,120	22,009	0.1	6,115,157
Dairy Cow Replacement	5,400	3,555	0.1	871,544
Dairy Cows	8,640	9,690	0.1	3,800,961
Steers, 500 lbs. and over	5,400	8,414	0.1	2,062,776
Bulls, 500 lbs. and over	5,400	1,579	0.1	387,108
Steers, Heifers and Bulls under 500 lbs.	2,520	19,591	0.1	2,241,367
Stock Sheep	1,088	3,308	0.1	163,375
Lambs	1,316	592	0.1	35,358
Total	41,284	73,404		16,821,563

1) Includes all states east of the western borders of Minnesota, Arkansas, Louisiana plus California and Oregon.

2) Based on data published in USDA Agricultural Statistics 1975.

Table # 3

EFFECTS OF SELENIUM SUPPLEMENTATION ON TISSUE SELENIUM LEVELS IN SHEEP[1]

Selenium Fed in Complete Fattening Diet

Tissue[2]	Diet	Basal, Deficient (Natural)	Basal, Adequate (Natural)	Basal, Deficient + 0.1 ppm Se	Basal, Adequate + 0.2 ppm Se
		Levels of Selenium in Tissue (ppm)			
Sternomandibularis m[2]		.088[a]	.167[d]	.092[ab]	.110[abc]
Liver[3]		.242[a]	.618[cd]	.380[ab]	.533[bc]
Kidney[4]		1.207	1.301	1.261	1.223

Selenium Added as a Component of Trace Mineralized Salt Mixture to Fattening Lambs

Tissue	Diet	Basal, Deficient (Natural)	Basal, Adequate (Natural)	Basal, Deficient + 0.1 ppm Se	Basal, Adequate + 0.2 ppm Se
Sternomandibularis m		.070[a]	.135[c]	.086[ab]	.100[b]
Liver		.258[a]	.498[bc]	.384[ab]	.435[bc]
Kidney		1.483	1.458	1.372	1.366

1) Ullrey, D. E., 1976. Data submitted to FDA and contained in MF INAD 1807.

2) Values shown on a wet basis.

3) Significant ($P<0.01$) difference between diets by least square Analysis of Variance for unequal subclass numbers (Harvey, 1960) (1 muscle sample lost).

4) Mean differences were approximated with Tukey's honestly significantly difference procedure (Steel and Torrie, 1960), and means with different superscripts were judged significantly ($P<0.05$) different.

Table # 4

EFFECTS OF SELENIUM SUPPLEMENTATION ON TISSUE SELENIUM LEVELS IN BEEF CATTLE[1]

Selenium Fed in Complete Fattening Diet

	Levels of Selenium in Tissue (ppm)			
Tissue[2] / Diet	Basal, Deficient (Natural)	Basal, Adequate (Natural)	Basal, Deficient + 0.1 ppm Se	Basal. Adequate + 0.2 ppm Se
Sternomandibularis m[2]	.070[a]	.135[c]	.086[ab]	.100[b]
Liver[3]	0.258[a]	.498[bc]	.384[ab]	.435[bc]
Kidney[4]	1.483	1.458	1.372	1.366

1) Ullrey, D. E., 1976. Data submitted to FDA and contained in MF INAD 1807.

2) Values shown on a wet basis.

3) Significant ($P<0.01$) difference between diets by least square Analysis of Variance for unequal subclass numbers (Harvey, 1960) (2 steers removed before the end of the trial).

4) Mean differences were approximated with Tukey's honestly significantly difference procedure (Steel and Torrie, 1960), and means with different superscripts were judged significantly ($P<0.05$) different.

TABLE # 5

Selenium Content of Corn in Midwestern States[1]

State	Number of Samples	Selenium in parts per million: Low	High	Mean	Median
North Dakota	6	0.09	0.26	0.19	0.22
South Dakota	10	0.11	2.03	0.40	0.24
Nebraska	6	0.04	0.81	0.35	0.28
Kansas	1	---	0.99	---	---
Minnesota	22	0.02	0.29	0.09	0.06
Iowa	25	0.02	0.16	0.05	0.05
Missouri	4	0.02	0.09	0.05	0.05
Wisconsin.	5	0.02	0.13	0.05	0.02
Illinois	31	0.02	0.15	0.05	0.04
Michigan	5	0.03	0.04	0.03	0.03
Indiana.	20	0.01	0.15	0.04	0.04
Total	135	0.01	2.03	0.11	0.05

1. Patrias, G. and O. E. Olson. 1969. Selenium Contents of Samples of Corn from Midwestern States. Feedstuffs: October 25 Issue.

TABLE # 6

The Geographic Distribution of Astragalus - A Selenium Accumulator Plant[1]

Species	Distribution
A. bisculatus	Montana, N. Dakota, S. Dakota, Idaho, Wyoming, Nebraska, Colorado, Oklahoma, Kansas, New Mexico
A. racemous Pursh	Montana, N. Dakota, S. Dakota, Wyoming, Nebraska, Colorado, Utah, Kansas, New Mexico, Oklahoma, Texas
A. osterhouti Jones	Colorado
A. argillosus	Utah, Arizona
A. grayi Parry	Wyoming, Montana
A. beathii Porter	Arizona

1. Rosenfeld, I. and O. A. Beath. 1964. Selenium: Geobotany, biochemistry, toxicity and nutrition. Academic Press, New York, page 62.

TABLE # 7

The Selenium Content of Plants
Grown on Seleniferous Soil[1]

Plant	Selenium Concentration (ppm)
Astragalus bisculatus	5,530
Stanleya pinnata	1,190
Astriplex nuttallii	300
Grasses	23

1. Rosenfeld, I. and O. A. Beath. 1964. Selenium: Geobotany, biochemistry, toxicity and nutrition. Academic Press, New York, page 91.

TABLE # 8

1975 RUMINANT LIVESTOCK POPULATION IN THE EASTERN U. S.[1 2] AND THE PACIFIC COAST AREAS BY SPECIES

States / Species	Beef Cow Replacements 1,000's	Beef Cows 1,000's	Dairy Cow Replacements 1,000's	Dairy Cows 1,000's	Steers, 500 lbs. and Over 1,000's	Bulls, 500 lbs. and Over 1,000's	Steers, Heifers and Bulls Under 500 lbs. 1,000's	Stock Sheep 1,000's	Lambs 1,000's
Alabama	257	1,238	30	92	208	59	762	3.6	0.8
Arkansas	252	1,259	27	91	102	91	791	4.3	1.2
California	286	1,097	285	800	1,144	88	1,310	810	100
Connecticut	2	7	18	55	2	2	22	4.4	1.1
Delaware	1	5	3	13	3	1	6	1.5	.4
Florida	265	1,468	44	202	136	100	676	3.3	.9
Georgia	184	1,060	42	130	179	68	692	2.8	.7
Illinois	144	868	93	257	640	63	841	158	37
Indiana	108	584	74	218	340	28	641	148	32
Iowa	272	1,835	147	405	1,580	96	2,317	306	64
Kentucky	334	1,429	95	296	319	109	1,037	34	6
Louisiana	183	909	37	134	55	61	422	11.2	3.8
Maine	4	12	25	60	2	3	30	10	3
Maryland	20	69	55	138	40	11	95	14	3
Massachusetts	2	8	17	55	3	2	19	5.4	1.3
Michigan	49	199	177	421	282	28	410	120	20
Minnesota	199	739	398	886	633	71	1,261	255	45
Mississippi	336	1,458	39	126	72	90	825	5.1	1.9
Missouri	551	2,759	109	311	632	156	2,037	135	23
New Hampshire	1	5	12	33	2	1	16	4.2	1.1
New Jersey	6	14	14	48	7	3	21	7.8	2.2
New York	36	125	345	920	36	31	343	57	14
North Carolina	107	416	43	152	61	37	266	9	2
Ohio	113	445	140	405	442	47	636	375	67
Oregon	116	617	28	91	126	42	395	303	52
Pennsylvania	49	176	236	686	260	59	417	101	24
Rhode Island	-	1	2	6	-	-	3	1.9	.6
South Carolina	67	305	12	59	46	27	178	1.1	.3
Tennessee	300	1,293	67	217	228	70	1,051	16	3
Vermont	4	14	62	192	3	5	52	4.9	1.5
Virginia	140	621	68	159	200	39	474	144	33
Washington	114	403	87	181	188	28	334	67	10
West Virginia	57	226	14	41	44	17	127	107	21
Wisconsin	107	345	710	1,810	399	46	1,084	77	15
Total	4,666	22,009	3,555	9,690	8,414	1,579	19,591	3,307.5	591.8
United States	8,879	45,421	4,095	11,216	16,378	2,987	36,342	10,553	1,927
% of Ruminant Livestock in the States Listed	53	48	86	86	51	53	54	32	30

1) Based on data published in USDA Agricultural Statistics 1975.
2) All states east of the western borders of Minnesota, Arkansas, Louisiana plus California and Oregon.

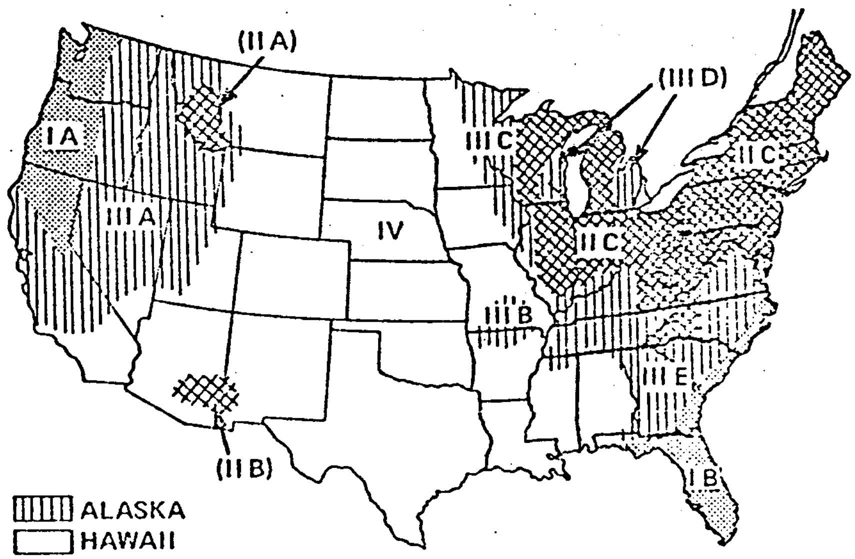
APPENDIX B

FIGURES

FIGURE I

AREA PATTERNS IN THE SELENIUM CONTENT OF PLANTS IN THE UNITED STATES

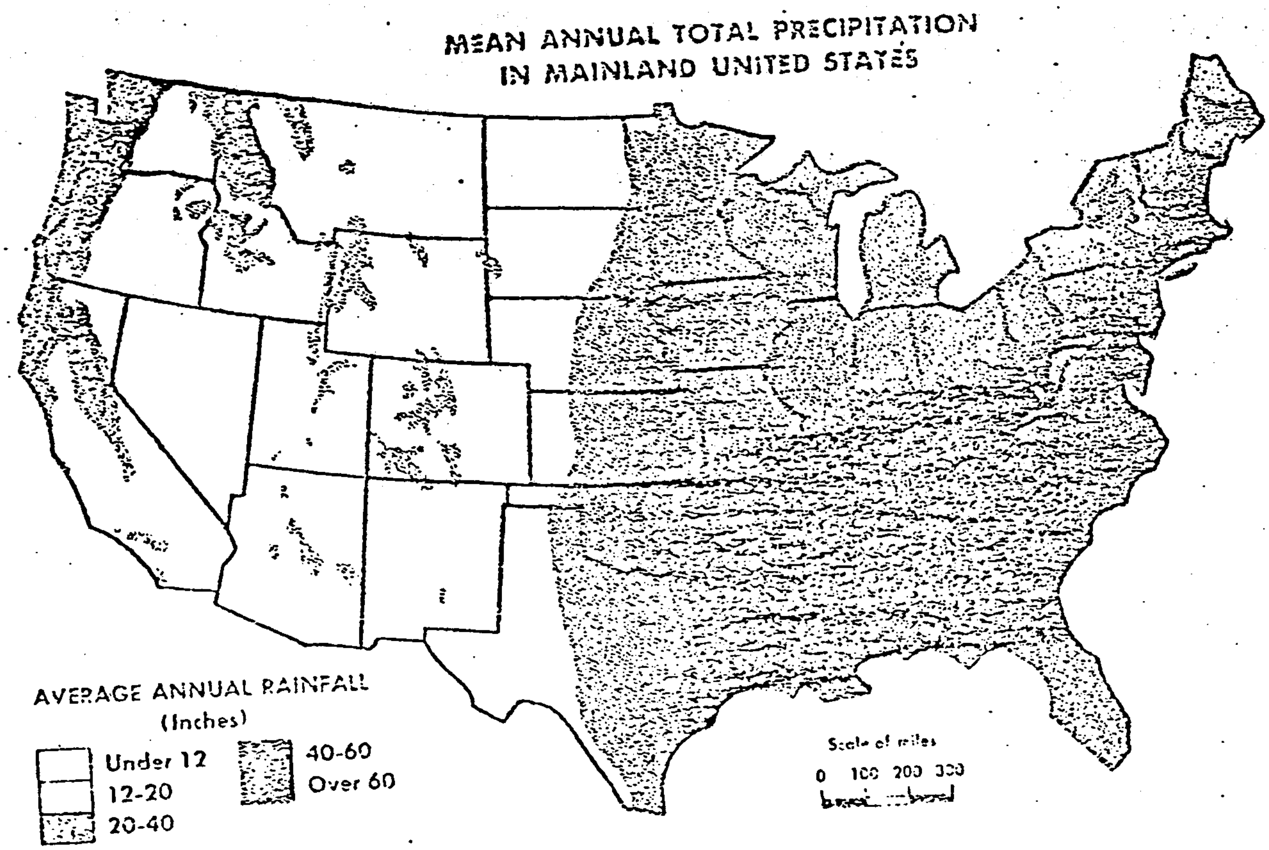
Figure 6 shows the concentrations of selenium in crops in different areas of the United States. A unique feature of the distribution of selenium in plants in the United States is the occurrence of several broad areas where almost all the plants sampled contained low levels



AREA	CROP	NO. OF SAMPLES	MEDIAN CONC	FREQUENCY DISTRIBUTION (%) OF SAMPLES WITH Se CONCENTRATIONS (ppm) OF: <0.01 to 0.05	0.05 to 0.10	0.10 to 0.50	0.50 to 1.0	1.0 to 5.0	>5
I A	FORAGES	69	0.03	81	15	4	0	0	0
I B	FORAGES	26	0.02	89	11	0	0	0	0
II A	FORAGES	14	0.05	50	36	14	0	0	0
II B	FORAGES	11	0.05	36	45	19	0	0	0
II C	FORAGES	187	0.05	65	31	4	0	0	0
III A	FORAGES	261	0.09	20	31	43	4	2	0
III B	FORAGES	14	0.05	57	14	22	0	7	0
III C	FORAGES	39	0.09	20	41	26	13	0	0
III D	FORAGES	27	0.10	26	18	49	7	0	0
III E	FORAGES	79	0.06	50	23	22	5	0	0
IV	FORAGES	205	0.26	3	10	60	18	9	0
	WHEAT	856	—	9		22	30	34	5
	FEED GRAIN	262	—		33		22	38	7

FIGURE 6 Relative concentrations of selenium in crops from different areas of the United States. Data for wheat and feed grain are from U.S. Department of Agriculture Technical Bulletin 758 (1941). From Kubota *et al.* (1967).

FIGURE II


MEAN ANNUAL TOTAL PRECIPITATION
IN MAINLAND UNITED STATES
AVERAGE ANNUAL RAINFALL
(Inches)
Under 12
12-20
20-40
40-60
Over 60
Scale of miles
0 100 200 300

APPENDIX C

ECONOMIC IMPACT

ECONOMIC IMPACT

Agricultural Statistics (USDA, 1975) showed that approximately 51% of beef cattle, 68.8% of dairy cattle, and 31% of the sheep produced in the United States are produced in "selenium deficient" states (Table 8). These percentages have been used in subsequent calculations to estimate the number of ruminant animals affected by selenium-deficient diets.

Selenium deficiency has been diagnosed for the increasing frequency in ruminant livestock over the past five years. No natural feed ingredients have been found to contribute adequate levels of selenium to provide an economical solution to this nutrient deficiency which now has widespread geographical occurrence. It is believed that marginal levels of selenium in feeds cause impaired performance in many herds in which no visible symptoms are observed.

Economic losses to livestock producers attributed to lack of approval for the addition of inorganic selenium to feeds may originate from: 1. Reduced calf crop, reduced weight gains, impaired feed conversion, increased incidence of reproductive diseases, and other losses which affect the well being of the animal. 2. Higher feed ingredient cost to increased natural selenium levels.

The following assumptions and estimates of economic losses represent an appraisal of the economic impact of selenium deficiency in beef, dairy, and sheep industries of the United States.

Beef Cattle

Assumptions: The following calculations are based on 46.5 million beef cattle being produced in 1975 in selenium deficient areas:

- 25% of beef cow replacements are affected to the extent of having the potential for producing 10% fewer calves.
- 25% of beef cows are affected to the extent of producing 10% fewer calves.
- 30% of steers show impaired growth and feed conversion (5% on growth and 5% on feed conversion).
- Above losses in addition to increased ingredient costs of \$0.50/ton in an attempt to alleviate deficiencies.

Economic Losses

Reduced Number of Calves :	Beef Cow Replacement 0.25 x 4,666,000 x 0.80 x 0.10 (av. calving %) @ \$75/calf =	\$ 6,999,000
	Beef Cows 0.25 x 22,009,000 x 0.80 x .10 (av. calving %) @ \$75/calf=	33,013,500
	Sub Total	\$ 40,012,500
Reduced Growth & Feed Conversion:	Reduced Growth 0.30 x 8,414,000 x 750 (av. wt.) = 1,893,150,000 lbs. beef produced 5% loss of weight = .05 x 1,893,150,000 = 94,657,500 @ \$.30/lb. =	\$ 28,397,250
	Reduced Feed Conversion 5% loss in feed conversion - .05 x 1,893,150,000 x 6.50 (av. feed conv.) = 615,273,750 lbs. feed @ \$.05/lb. =	30,763,687
	Sub Total	\$ 59,160,937
Added Feed Cost :	46,500,000 beef cattle consumed 119,426,000 tons of feed @ \$.50/ton =	\$ 59,713,000
	Total Annual Loss to Beef Cattle Producers	\$158,886,400

Dairy Cattle

Assumptions: **The following calculations are based on 23.0 million dairy cattle being milked and produced in selenium deficient areas:**

- **25% of dairy cow replacements and dairy cows are affected to the extent of having the potential for producing 10% fewer calves.**

- **25% of dairy cows show impaired milk production and feed conversion (10% on milk production and 3% on feed conversion).**

- **Above losses in addition to increased ingredient costs of 0.50/ton in an attempt to alleviate deficiencies.**

Economic Losses

Reduced Number of Calves :	0.25 x 13,245,000 x 0.80 (av. calving %) x 0.10 @ $70/calf =	$ 20,397,300
Reduced Milk Production & Feed Conversion:	0.25 x 9,690,000 x 10,600 (av. production) x 0.10 = 2,567,850,000 lbs. milk lost @ $8.60/100# =	$220,835,100
	3% loss in feed conversion - 0.03 x 0.8150 (lbs. feed/lb. milk) x 25,678,500,000 lbs. milk = 627,840,540 lbs. feed lost @ $.04/lb. =	25,113,621
	Sub Total	$245,948,721
Added Feed Cost :	23,000,000 dairy cattle consumed 224,882,300 tons of feed @ $.50/ton =	$112,441,150
Total Annual Loss to Dairy Cattle Producers		$378,787,171

Sheep

Assumptions: The following calculations are based on 3.9 million sheep being produced in 1975 in selenium deficient areas:

- 25% of stock sheep are affected to the extent of producing 10% fewer lambs.
- 30% of lambs show impaired growth and feed conversion (5% on growth and 5% on feed conversion).
- Above losses in addition to increased ingredient costs of $.50/ton in an attempt to alleviate deficiencies.

Economic Losses

Reduced Number of Lambs :	0.25 x 3,308,000 x .85 (av. lambing %) x 0.10 @ $25 =	$1,757,375
Reduced Growth & Feed Conversion:	Reduced Growth 0.30 x 3,308,000 x 100 (av. wt.) = 99,240,000 lbs. lamb produced 5% loss of weight = 0.05 x 99,240,000 = 4,962,000 @ $.40/lb. =	1,984,800
	Reduced Feed Conversion 5% loss in feed conversion - 0.05 x 3,308,000 x 3.50 (av. feed conv.) = 17,367,000 lbs. feed @ $.05/lb. =	868,350
Added Feed Cost :	3,900,000 sheep consumed 9,375,600,000 lbs. of feed @ $.50/ton =	2,343,900
Total Annual Loss to Sheep Producers		$6,954,425

APPENDIX D

LIST OF REFERENCES

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